

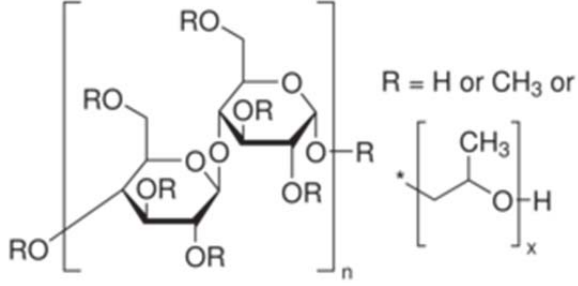
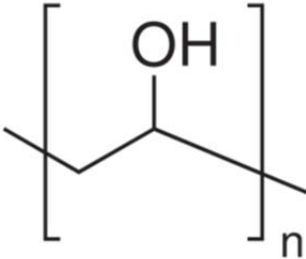
**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

| | | |
|----------------------------------|---|---------------------|
| AUXILIUM PHARMACEUTICALS, INC. |) | |
| and FCB I, LLC, |) | |
| |) | |
| Plaintiffs, |) | |
| |) | |
| v. |) | C.A. No. 13-148-SLR |
| |) | |
| UPSHER-SMITH LABORATORIES, INC., |) | |
| |) | |
| Defendant. |) | |

**PLAINTIFFS’ SUPPLEMENTAL SUBMISSION IN OPPOSITION TO UPSHER-SMITH
LABORATORIES, INC.’S MOTION FOR SUMMARY JUDGMENT**

Pursuant to the Court’s direction at the June 28, 2013 oral argument, Plaintiffs hereby submit Federal Circuit precedent demonstrating that the doctrine of equivalents can, and in this case should, reach an equivalent that has a significantly different chemical structure than its counterpart in the asserted claim. Here, USL uses a combination of three penetration enhancers (inactive ingredients) in place of the claimed “Hsieh” enhancers. As demonstrated below, the differences in chemical structure between these enhancers do not constitute a legal barrier preventing Plaintiffs from proving infringement under the doctrine of equivalents.

In *SmithKline Beecham Corp. v. Excel Pharmaceuticals, Inc.*, the Federal Circuit reversed a district court’s grant of summary judgment on amendment-based estoppel grounds, holding that there were issues of material fact concerning whether the asserted equivalent was foreseeable. 356 F.3d 1357, 1360 (Fed. Cir. 2004). The patent-in-suit claimed a sustained release formulation, the “key ingredient” in which was a compound called hydroxypropyl methylcellulose (HPMC). *Id.* at 1359. As illustrated below, HPMC and its asserted equivalent (polyvinyl alcohol) have significantly different chemical structures:

| Claim Language: hydroxypropyl methyl-cellulose (HPMC) | Asserted Equivalent: polyvinyl alcohol (PVA) |
|---|--|
|  |  |

Despite these structural differences between the claimed compound and the asserted equivalent, the Federal Circuit vacated the District Court’s grant of summary judgment of noninfringement based on prosecution history estoppel, and permitted the plaintiff’s doctrine of equivalents case to proceed. “Because foreseeability ‘depends on underlying factual issues,’ . . . this court remands to facilitate development of the record on this key point.” *SmithKline Beecham Corp.*, 356 F.3d at 1365 (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003)).

In addition, in *Abbott Laboratories v. Andrx Pharmaceuticals, Inc.*, the Federal Circuit affirmed a preliminary injunction based on infringement under the doctrine of equivalents, despite the fact that the accused equivalent was significantly different than the claimed class of compounds. In that case, the relevant patent claimed extended release formulations comprising erythromycin derivatives combined with a “pharmaceutically acceptable polymer.” 473 F.3d 1196, 1199 (Fed. Cir. 2007). The specification explained that the claimed polymer “is a water-soluble hydrophilic polymer selected from the group consisting of polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acid copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof.” *Id.* at 1208 (quoting U.S. Pat. No. 6,010,718, at 3:65–67,

4:1–4.) As illustrated below, and as agreed by the parties, Andrx’s product did not contain a polymer at all, but instead used an acyclic hydrophobic non-polymeric compound called glyceryl monostearate (“GMS”).

| Claim Language: “pharmaceutically acceptable polymer” (Examples from Specification) | Asserted Equivalent: Glyceryl Monostearate (GMS) |
|--|---|
| <div data-bbox="381 535 690 745" data-label="Chemical-Block"> </div> <p data-bbox="191 745 852 787">maleic anhydride/methyl vinyl ether copolymers</p> <div data-bbox="227 808 406 1039" data-label="Chemical-Block"> </div> <p data-bbox="267 1071 332 1113">PVP</p> <div data-bbox="568 808 795 966" data-label="Chemical-Block"> </div> <p data-bbox="560 997 836 1039">R = H or CH₂CH(OH)CH₃</p> <p data-bbox="519 1071 860 1113">hydroxypropyl cellulose</p> | <div data-bbox="885 661 1437 766" data-label="Chemical-Block"> </div> |

Id. at 1207–08. The Federal Circuit affirmed the district court’s grant of a preliminary injunction, holding that Abbott had showed a likelihood of success of proving infringement under the doctrine of equivalents *despite* Andrx’s argument that its equivalent GMS was a “hydrophobic, non-polymeric substance” and the “antithesis of the required polymer.” *Id.* at 1212–13.

These are two cases that demonstrate most clearly that Plaintiffs should be permitted the opportunity to prove at trial that USL infringes Plaintiffs’ patents under the doctrine of equivalents. There are also additional cases that—while they do not involve equivalence between formulations with non-cyclic compounds and cyclic compounds—leave open the doctrine of equivalents for compounds that are substantially different from the compound

expressly claimed in the invention.¹ Moreover, plaintiffs have found no case suggesting a *per se* rule barring assertion of infringement under the doctrine of equivalents simply because the chemical structure of the proposed equivalent is significantly different from that of the claimed compound.² Put another way, if the plaintiff in *Abbott* established a “likelihood of success” of showing infringement by equivalence between a polymer and a non-polymer, there is no basis to conclude on this record that Plaintiffs have not at least raised a *triable issue of material fact* as to whether USL’s three-enhancer combination system is equivalent to the claimed Hsieh enhancers. *Cf. Leggett & Platt, Inc. v. Hickory Springs Mfg. Co.*, 285 F.3d 1353, 1359-60 (Fed. Cir. 2002) (reversing grant of summary judgment of non-infringement under the doctrine of equivalents: “Because infringement under the doctrine of equivalents often presents difficult factual determinations, a summary conclusion that a reasonable jury could not find infringement is often illusive.”). Consideration of the relevant chemical structures might be relevant to the ultimate infringement inquiry, but that question is not ripe for summary judgment—indeed, it has not yet even been briefed by the parties.

Finally, the alleged legal barriers to asserting the doctrine of equivalents raised by USL, such as prosecution history estoppel, ultimately turn on whether the proposed equivalent was foreseeable. But here, USL itself argues that its three-enhancer combination system was

¹ *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364 (Fed. Cir. 2005) (affirming a district court’s grant of a preliminary injunction where the patent claimed either a mono- or disaccharide and the alleged equivalent was microcrystalline cellulose (essentially, sawdust), which is a polysaccharide); *Glaxo Wellcome v. Pharmadyne Corp.*, 32 F. Supp. 2d 265 (D. Md. 1998) (finding infringement under the doctrine of equivalents where propylene glycol was determined to be equivalent to ethanol).

² In *Wrigley*, the inventor was introduced to both the claimed compound and the asserted equivalent “during the same sales call, and they were told that the two compounds were appropriate for the same uses.” *W.M. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1366 (Fed. Cir. 2012). Thus, the manifest foreseeability of the equivalent precluded application of the doctrine of equivalents.

unforeseeable (indeed, USL contends that its combination enhancer system is *novel*). Thus, there can be no legal bar to asserting infringement in this case.

For these reasons, in addition to those stated in Plaintiffs' opposition papers and at oral argument, summary judgment should be denied and the parties should be given the opportunity to provide factual evidence of the applicability of the doctrine of equivalents at trial.

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